510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

InnerSense Esophageal Temperature Probe/ Feeding Tube

Submitter's Name and Address

Submitter's Name:	Philips Medical Systems
Division:	PCCI - Medical Consumables and Sensors
Address:	3000 Minuteman Road
City, State, and Zip:	Andover, MA 01810

Contact Person / Submission Correspondent

OCT 2 3 2013

Name:	Christine Trefethen
Title:	Regulatory Specialist
Telephone:	(978) 659-3890
Facsimile:	(978) 659-7712
E-mail:	christine.trefethen@philips.com

Date of Summary

Date:	September 16, 2013

Manufacturers' Information

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road Andover, MA 01810
Establishment Registration No.	1218950

New Device Details

Proprietary or Trade Name:	InnerSense Esophageal Temperature Probe / Feeding Tube
Common Name:	Temperature Probe/ Feeding Tube
Device Class:	Class II
Device Procode:	FPD
Device CFR:	21 CFR 876.5980

Classification Panel:	Gastroenterology/Urology
Classification Name:	Gastrointestinal tube and accessories

Predicate Device Details

510(k) Number	K120815
Proprietary or Trade Name:	InnerSense Esophageal Temperature / Feeding Tube
Common Name:	Feeding Tube/ Temperature Probe
Device Class:	Class II
Device Procode:	FPD
Device CFR:	21 CFR 876.5980
Classification Panel:	Gastroenterology/Urology
Classification Name:	Gastrointestinal tube and accessories

Device Description

The InnerSense Esophageal Temperature Probe/ Feeding Tube is a single- use, disposable, sterile device designed for nasogastric or orogastric placement in neonatal or pediatric patients. It is used to continuously monitor esophageal temperature, deliver oral medications and/or provide enteral feeding to a patient for up to 30 days. The InnerSense Esophageal Temperature Probe/ Feeding Tube can be used in neonates or children solely for temperature monitoring; it is not intended to be exclusively used for children who require enteral feeding. The device should be applied only under direct supervision of a licensed physician or healthcare provider and be safely connected only to an enteral giving set or syringe and the compatible patient monitor.

Indications for Use

The InnerSense Esophageal Temperature Probe/Feeding Tube is a dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.

Comparison of Technological Characteristics:

The proposed device shares the same fundamental scientific technology, indications for use, and operating principles as the predicate device.

A summary comparison of the technological characteristics between the proposed device and the predicate device is as follows:

Specification	Philips InnerSense Esophageal Temperature / Feeding Tube (Predicate Device)	Philips InnerSense Esophageal Temperature Probe/ Feeding Tube (Proposed Device)	Comparison
Indications for Use	Dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.	Dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.	Same
Lumen Construction	Dual Lumen	Dual Lumen	Same
Method of Sterility	EtO Sterilization	EtO Sterilization	Same
Thermistor type	Series 400	Series 400	Same
Offered diameters	5, 6.5 and 8Fr.	5, 6.5 and 8Fr.	Same
Feeding Connector Materials	Polyvinyl Chloride (PVC)-Orange colorant	Polyurethane-Orange colorant Polyurethane-Purple colorant	The feeding connector materials were tested in accordance with ISO 10993. The results of the 10993 biocompatibility testing proved that the patient contacting materials for the proposed device have the same toxicological, sensitization, irritation, and acute toxicity profile as the previously cleared device. Thus, the feeding connector materials are substantially equivalent to the feeding connector materials used in the predicate device.

Specification	Philips InnerSense Esophageal Temperature / Feeding Tube (Predicate Device)	Philips InnerSense Esophageal Temperature Probe/ Feeding Tube (Proposed Device)	Comparison
Catheter Materials	Clear Polyurethane-Orange colorant+ ink	Clear Polyurethane-White (TiO2)+ ink	The feeding connector materials were tested in accordance with ISO 10993. The results of the 10993 biocompatibility testing proved that the patient contacting materials for the proposed device have the same toxicological, sensitization, irritation, implantation, and acute toxicity profile as the previously cleared device. Thus, the feeding connector materials are substantially equivalent to the feeding connector materials used in the predicate device.
Distal tip	One lateral eye, one end eye in catheter tip	2 offset lateral eyes, closed catheter tip	The distal tip was tested in accordance with EN 1615 and ISO 80601-2-56. The results of EN 1615 testing proved that the distal tip attributes of the proposed device exhibited equivalent tensile strength properties to that of the predicate device. Performance testing results proved that the proposed device performance was equivalent to that of the predicate device. All tests passed, thus the revised distal tip is substantially equivalent to the predicate device.

Specification	Philips InnerSense Esophageal Temperature / Feeding Tube (Predicate Device)	Philips InnerSense Esophageal Temperature Probe/ Feeding Tube (Proposed Device)	Comparison
Temperature/ Accuracy Range	± 0.1°C from 25°- 45°C	± 0.1°C from 32°- 43°C, and ± 0.2°C from 25°- 45°C	The thermistor type is identical between the proposed device and the predicate device. The minor difference in temperature accuracy range is due to the fact that the predicate device was tested in accordance with EN 12470-4 and the proposed device was tested in accordance with ISO 80601-2-56. The proposed device was tested and meets the clinical accuracy range of ISO 80601-2-56, applicable to the indicated patient population, thus the revised temperature accuracy range is substantially equivalent to that of the predicate device.

The proposed device is considered substantially equivalent to the predicate device based on the results of the non-clinical performance tests conducted. All technological differences between the proposed device and the predicate have been evaluated through extensive verification tests (see Non-clinical Performance data section below) which concluded that the modifications to the device do not raise any new issues of safety and effectiveness.

Non-clinical Performance Data:

Extensive verification of the device modifications was conducted and successfully completed. All performance tests demonstrated that the InnerSense Esophageal Temperature Probe / Feeding Tube performed as per its intended use and is substantially equivalent to the predicate device. Bench testing was performed in accordance with the following standards in order to support the substantial equivalence determination:

Standards
ISO 80601-2-56:2009 - Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN1615: 2000- Enteral feeding catheters and giving sets for single use and their connectors- Design and Testing
ISO 80369-1-1: 2010- Small-bore connectors for liquid and gases in healthcare applications- Part 1: General Requirements

Standards
ISO 11607-1-1: 2006- Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 10993-5: 2009- Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2007- Biological evaluation of medical devices- Part 6: Tests for local effects after implantation
ISO 10993-7: 2008- Biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010- Biological evaluation of medical devices-- Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11: 2006- Biological evaluation of medical devices-- Part 11: Tests for systemic toxicity
ISO 10993-18: 2005- Biological evaluation of medical devices-- Part 18: Chemical characterization of materials

Substantial Equivalence Conclusion

The Philips InnerSense Esophageal Temperature Probe/ Feeding Tube does not change the indications for use or the fundamental scientific technology, when compared to the legally marketed predicate device. Any differences between the proposed device and the predicate were evaluated to have no impact on the safety or effectiveness of the InnerSense Esophageal Temperature Probe / Feeding Tube and therefore it is considered substantially equivalent to the device cleared under Premarket Notification K120815.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 23, 2013

Philips Medical Systems
% Christine Trefethen
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, MA 01810

Re: K131590
Trade/Device Name: InnerSense Esophageal Temperature Probe/ Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: September 16, 2013
Received: September 17, 2013

Dear Christine Trefethen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 Indications for Use Statement

PHILIPS

510(k) Number: K131590

Device Name: **InnerSense Esophageal Temperature Probe/ Feeding Tube**

Indications for Use:

The InnerSense Esophageal Temperature Probe/Feeding Tube is a dual function, single-use sterile device which simultaneously provides continuous monitoring of esophageal temperature and delivers oral medications and/or enteral nutrition in neonatal and pediatric patients oro/nasogastrically, as directed by a physician for up to 30 days. The InnerSense device can be used solely for the purpose of monitoring esophageal temperature in situations where invasive monitoring is indicated.

Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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